

REMARKS

Applicants thank Examiner Kim for removing the requirement for election of species. However, the pending Office Action has withdrawn claims 38-58 from consideration despite the prior showing that consideration of all claims would not present a significant extra burden. While Examiner Kim is correct that a showing of separate classification is “prima facie” evidence of extra burden, given the substantially identical search requirements and similar area of subject matter, any such “prima facie” showing is rebutted. Accordingly, the examiner is respectfully requested to reconsider the restriction requirement and examine claims 38-58.

The pending Office Action objected to claims 21 and 22. In particular, an inconsistency was alleged between the preamble of independent claim 1, which recites “a tether,” and the body of its dependent claims 21 and 22, which include language directed to the bone portions recited in claim 1. Applicants disagree with the Office Action’s analysis of claims 21 and 22, particularly insofar as it suggests that those claims positively recite bone portions. Those claims do not claim non-statutory subject matter, and are proper as they stand. The claim language quite clearly identifies particular placement of the recited tether. Notwithstanding the fact that claims 21 and 22 are proper, in the interest of moving this application more quickly toward issue, claims 21 and 22 are amended as indicated above to obviate the allegation of inconsistency. No change in the scope of the claim has been made or is intended.

Turning to the substance of the Office Action, each claim has been initially rejected under Section 103 as allegedly obvious over U.S. Patent No. 6,137,060 to Avellanet and U.S. Patent No. 5,296,292 to Butters, alone or in combination with one of four tertiary references.

Respectfully, a prima facie case of obviousness has not been presented for any of the claims in this application, and therefore the obviousness rejections should be withdrawn.

A. The references are non-analogous to each other and this application

“In order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” MPEP 2141.01(a)(I) (internal quotations and citations omitted). To show the “reasonably pertinent” prong of that test, the PTO must show that a person of ordinary skill would reasonably be expected or motivated to look to an out-of-field reference. See MPEP 2141.01(a)IV.

The Avellanet reference is neither in the Applicants’ field of endeavor, nor is it reasonably pertinent to any problem with which they were concerned. Avellanet discloses a flexible, small diameter radiopaque wire suitable for use as a guidewire or in a stent. Avellanet, column 3, lines 1-3. The wire is made by crushing together several filaments and annealing them, so that the resulting wire has a flexibility the same as or greater than a single-strand nickel-titanium wire with a greater density and better conductivity characteristic. *Id.* at column 3, line 57-column 4, line 17. The present application, conversely, is concerned with tethers intended to secure bone portions. Avellanet does not state or even hint at use in securing bone portions to one another. It cannot be legitimately suggested that because Avellanet suggests a medical use for its wire, it is analogous to the present application’s bone tether. For substantially the same reasons, Avellanet cannot be said to be “reasonably pertinent” to issues facing the inventors of the present application. It concerns a specific formulation of wire for guidewires and stents. It

does not address issues surrounding securing adjacent bone portions, having the claimed degree of tensile strength, or other aspects of this application. Avellanet also does not address the more general problems associated with single cables or braids of surgical cord noted in the background of the present application. Moreover, the Office Action does not make any showing as to why one of skill would be motivated to look at stent wires to help solve problems with bone tethers. See MPEP 2141.01(a) (citing In re Oetiker, 977 F.2d 1443 (Fed. Cir. 1992)) (no evidence that one interested in hose clamps would look to garment fastener art). Because Avellanet is neither in Applicants' field nor "reasonably pertinent" to their disclosure, it cannot properly be used in an obviousness rejection.

The Butters reference is neither in the Applicants' field of endeavor, nor is it reasonably pertinent to any problem with which they were concerned. Butters discloses a multiple layer fishing line. Butters, column 1, lines 5-8 et seq. The fishing line is generally a core of PTFE or similar materials, either monofilament or braided together, surrounded by a layer of PTFE. The fishing line is made by extruding PTFE around the core, heating, and sizing. The fishing line has a low coefficient of friction, can float high, is hydrophobic, and has very little "memory," among other characteristics. See id. at column 4, line 60-column 5, line 4. Butters does not state or even hint at using its fishing line in any medical application, much less securing bone portions to one another. There is simply no possible ground for claiming that Butters is analogous to the present application. Similarly, there is no ground for asserting that Butters' fishing line is in the same field of endeavor as Avellanet's stent wire. Butters also cannot be said to be "reasonably pertinent" to issues facing the inventors of the present application. It concerns a specific formulation of fishing line, and does not address issues surrounding securing adjacent bone

portions, having the claimed degree of tensile strength, or other aspects of this application. Indeed, Butters' example states that its fishing line breaks at about 25 pounds, much less than would be required in an orthopedic environment. Moreover, the Office Action does not make any showing as to why one of skill would be motivated to look at fishing line to help solve problems with bone tethers. See MPEP 2141.01(a). Because Butters is not in Applicants' or Avellanet's field, and it is not "reasonably pertinent" to the present application, it cannot properly be used in an obviousness rejection.

The remaining references, U.S. Patent No. 4,146,022 to Johnson, U.S. Patent No. 6,338,734 to Burke, U.S. Patent No. 4,643,178 to Nastari, and U.S. Patent No. 3,968,725 to Holzhauer, also are outside of the tether field of the present application. Johnson's cerclage tacks, Burke's femoral plate, and Nastari's cerclage wire cannot legitimately be suggested to be analogous to Avellanet's stent wire or each other merely because they have some connection to medicine or wire. Holzhauer's water-ski rope (see column 4, lines 42-54) is not in the same field as any of the other references. For at least these reasons, these tertiary references are also believed to be improperly used in the pending rejection.

To summarize, the PTO has not sustained its burden to show that the cited references are analogous to the present application and each other. Avellanet and Butters are combined in rejecting every examined claim in this application, and as discussed above, there is no basis for their use in an obviousness rejection in this case. Similarly, no proper basis for introducing the four tertiary references into this case, and no showing of analogousness of them to Avellanet and Butters (and the present application), has been provided. On at least these grounds, the cited references and the obviousness rejections based on them should be withdrawn.

B. There is no proper motivation to combine the references against this applicaiton

As another ground for withdrawing the present rejections, a proper motivation to combine the references has not been provided. In order to make a proper obviousness challenge, a motivation must be shown to combine the references, and the desirability of the combination must also be shown. Such motivation and desirability must come from the references or other information outside of the disclosure of the application under examination. The application cannot be treated as a “parts list” guiding the search for items in references; reference to the application for a rationale to combine references is the essence of impermissible hindsight.

In discussing claims 1, 36 and 37, the Office Action refers to recitation of “abrasion resistant” in Butters, and jumps from there to the conclusion that one would “construct the invention of Avellanet in view of Butters, in order to make a tether last longer and maintain its tensile strength.” Respectfully, that statement is ambiguous at best, and cannot represent a legitimate motivation to combine the references. The Office Action does not explain what is meant by constructing the Avellanet device “in view of” Butters. Assuming that phrase to mean placing a porous expanded PTFE layer on the Avallanet wire, there is no indication that one of ordinary skill could accomplish that feat given the disclosures of the individual references. Avellanet states that its wire is to be drawn and annealed at about 500 degrees at the same time (column 4, lines 4-9), while Butters states that PTFE is to be extruded onto a non-metallic core and sintered to 400 degrees (column 3, line 66-column 4, line 15). Reheating the Avellanet wire in placing Butters’ PTFE layer goes against the teaching of Avellanet, and can negatively affect the annealed characteristics of the wire. In addition, the Avellanet reference does not suggest that its wire needs to “last longer” or “maintain tensile strength,” and its uses as a guidewire or in

a stent do not suggest such needs. Likewise, the Butters reference does not suggest use with metals. Further, it is not logical to suggest that a thin PTFE layer, as in Butters, added to a metal wire would maintain the wire's tensile strength, because the PTFE layer would break or fail long before the wire on application of tension. For at least these reasons, there is no motivation evident in the Avellanet or Butters references to combine them as the Office Action suggests.

As another example, the Office Action in discussing claim 4 states only that Butters teaches use of an adhesive layer, and leaps to the conclusion that it would have been obvious to construct "the sheath of Avellanet in view of" an adhesive layer "to frictionally engage the two sheaths." The language "frictionally engage" is not found in either of the Avellanet or Butters references, but only in the present application. This is clear evidence of using the present application as a template to assemble parts of references into a rejection, and constitutes impermissible hindsight.

With respect to claims 8, 9 and 11-14, the Office Action does not give a motivation to change the Avellanet reference, but merely suggests that rearranging or duplicating parts would be obvious. Such grounds are not sufficient to establish a motivation for change or a *prima facie* obviousness case "without some objective reason" to modify the reference. See MPEP 2143.01(IV) (case citation omitted). Since no motivation to move the high density portion or provide multiple such portions in the Avellanet wire was given, there can be no *prima facie* case of obviousness of claims 8, 9 and 11-14. Moreover, moving the gold, silver or platinum-iridium center strand to the outside, and a nickel-titanium strand to the inside, would fundamentally change the nature of the end-product wire. In the Avellanet wire, a center strand having one set of characteristics is surrounded by multiple strands of the same material and thus having a

mutual second set of characteristics. The result is an inner strand and a substantially homogeneous outer layer. Switching the positions of an inner and outer strand, or adding a second gold strand to the outside, would result in a non-homogeneous exterior, contrary to Avellanet's teachings. Thus, not only is there no motivation provided for the change suggested, in this case what the Office Action characterizes as rearranging or duplicating parts in fact cannot be obvious, because it goes against the teachings of the reference.

As to claims 20, 24-28 and 33-34, the Office Action again does not provide a motivation to change the materials used in the Avellanet and Butters references, but only claims that it is obvious to select materials based on "suitability for the intended use." Again, no "objective reason" to modify the reference was provided, as MPEP 2143.01(IV) requires. In this case, the Avellanet and Butters devices are not tethers for use in securing bone portions, and thus an analysis of the "intended use" of those references must consider that they are wholly different from the disclosed and claimed subject matter. Further, as to claim 20, there is no suggestion in either reference that "elastomeric material" is suitable for the stent or guidewire uses for the Avellanet wire or for the fishing line use in Butters. In fact, an elastomeric material used for Avellanet could defeat the sturdiness and radiopacity of the stent wire, and could be too malleable for use as Butters' fishing line. As to claims 24-28 and 33-34, the Office Action relies solely on Butters, and claims that one can make Butters with a radiopaque element, and that element can be of biocompatible metallic fiber. There is no reason to include a radiopaque element in fishing line, and using metallic fiber in fishing line would render the line too expensive to manufacture and could negatively affect its flexibility. Without a stated motivation

from the references, and since the Office Action's basis for changing Butters and Avellanet is not supportable, there is yet a further reason to withdraw the rejections of these claims.

With respect to claims 24-28 33-34, the Office Action does not give a motivation to change the Avellanet reference, but merely suggests that rearranging or duplicating parts would be obvious, without an objective reason to modify the reference. Since no motivation to move the high density portion or provide multiple such portions in the Avellanet wire was given, there can be no prima facie case of obviousness of claims 8, 9 and 11-14. Moreover, moving the gold, silver or platinum-iridium center strand to the outside, and a nickel-titanium strand to the inside, would fundamentally change the nature of the end-product wire. In the Avellanet wire, a center strand having one set of characteristics is surrounded by multiple strands of the same material and thus having a mutual second set of characteristics. The result is an inner strand and a substantially homogeneous outer layer. Switching the positions of an inner and outer strand, or adding a second gold strand to the outside, would result in a non-homogeneous exterior, contrary to Avellanet's teachings. Thus, not only is there no motivation provided for the change suggested, in this case what the Office Action characterizes as rearranging or duplicating parts in fact cannot be obvious, because it goes against the teachings of the reference.

In addition to the examples given above regarding the lack of motivation to combine Avellanet and Butters, the Office Action does not suggest any motivation to combine one or both of them with the tertiary references. With respect to claims 15-18, the Office Action is silent as to why one of ordinary skill would add changes from the Holzhauer ski-rope. The Office Action proposes combining Avellanet and Butters with Holzhauer, which the Office Action claims shows a second sheath that is movable with respect to a first sheath or a cord. It is clear that

Avellanet and Butters disclose stent wire and fishing line in which their respective layers are fixed with respect to each other. Further, changing either reference with the alleged teaching of Holzhauser of a movable “sheath” goes against the specific teaching of crushing wires together (in Avellanet) and extruding molten plastic over a central layer (in Butters).

With respect to claims 19 and 22, the Office Action suggests combining the Burke reference to Avellanet and Butters “in order to use a better tether to attach bone portions, which are too small for plate and anchors, together.” This statement is not understood, since Burke shows use of a plate wired to a femur. Moreover, there is nothing in Avellanet or Butters to suggest use to secure bone portions, and there is nothing in Burke to suggest changing the structure of the Avellanet stent wire or the Butters fishing line. As to claim 21, the Office Action is silent as to how the Nastari reference fits in, or of any motivation to consult it. Rather, the discussion of claim 21 concerns combining the Burke reference with Avellanet and Butters, and has been rebutted above. Moreover, neither the Avellanet nor the Butters reference hints at use of their stent wire or fishing line on vertebrae.

As to claims 29-32, there is no suggestion of how the Johnson reference would provide “better means to secure the tether to the bone portions,” as the Office Action posits, much less how its tack could be used with the stent wire of Avellanet or the fishing line of Butters. In fact, the language for this supposed motivation comes from the present application, and is another clear indication of impermissible hindsight. The discussion of claims 31 and 32 goes even farther afield, suggesting that one of ordinary skill would be motivated to dissociate parts of the Avellanet wire. That is plainly contrary to the teaching of the Avellanet reference. Further, the Office Action suggests that having alleged “sheaths” in an unnamed one of the references not

secured to bone portions is merely rearranging parts. As previously explained, it is not rearranging parts, it is changing the method of operation of the Avellanet and Butters references, and is simply not something one of skill in the orthopedic arts would be motivated to do.

Because of the wholesale difference between Avellanet's stent wire and the Butters fishing line, the source of any motivation to combine them is the present application. As noted above, the references are not analogous to each other or to the present application, and thus one of skill in the field of the present application or one of skill in the field of stent wires would not even consider Butters. Moreover, there is no suggestion in Avellanet that an outer layer placed on it would improve it or otherwise be useful. Rather, increasing the diameter of the Avellanet wire with an outer layer could limit its usefulness as a guidewire or stent wire, where diameters are kept small to enable items to be guided over the guidewire or to enable openings in a stent wall. There is also no suggestion in Butters to place its porous expanded PTFE layer around a metal wire, and doing so would render the result unfit for use as fishing line. Only by having knowledge of the present disclosure, and by considering stent wire and fishing line to be orthopedic tethers, could one attempt to combine Avellanet and Butters.

Respectfully, it appears that the Office Action has used the present application as a template, and has searched for references from which disparate elements can be picked and forced to fit the pending claims. That is not a proper obviousness analysis. A proper analysis must begin with the references, to see whether they are like enough so that a person of ordinary skill would see that one can be used in connection with another. No one of ordinary skill in the orthopedic field would see a stent wire, a fishing line, a water-ski rope, wires and tacks for vertebral cerclage, and a femoral repair system, and from those items create the orthopedic tether

recited in the present claims. While the PTO may assert that obviousness necessarily involves hindsight, that position is not conceded, and moreover the use of the present application as a parts list for finding references is the essence of impermissible hindsight.

The above examples are not intended to be comprehensive or exhaustive. Rather, they are provided as the most expedient demonstration that a prima facie case of obviousness has not been made out due to a lack of motivation to combine and change the cited references as the Office Action proposes.

C. The desirability of the combinations of references has not been demonstrated

In order to make a legitimate case of obviousness, the examiner must show the desirability of the combination, or why the person of ordinary skill would use the two references together. MPEP 2143.01(III) (“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination” (case citation omitted, emphasis in original)). In this case, the Office Action did not show that modifying Avellanet’s wire with parts of Butters’ fishing line would be desirable to a person of ordinary skill in the orthopedic arts. Bearing in mind that neither Avellanet nor Butters have anything to do with securing bone portions in orthopedic treatments, it is not possible for one in that field to find it desirable to combine those references in the way the Office Action suggests. The discussion above shows the incompatibility of the references in several ways. Without any statement as to desirability of combining Avellanet and Butters, much less of putting their stent wire and fishing line together with femoral plates, water-ski rope, or cerclage implements, the obviousness rejections cannot stand.

D. The references do not show all elements of the claims

Furthermore, it is clear from a review of the references that multiple aspects of the claims of this application are not shown in them. Much of the discussion above demonstrating the non-analogousness of the references is also applicable here. For completeness, however, a discussion of some aspects of the claims missing from the references follows.

With respect to claim 1, neither Avellanet nor Butters shows a surgical tether for orthopedic treatment to secure to two adjacent bone portions, as they must do. See MPEP 2111.02. As noted above, Avellanet discloses a stent wire and Butters discloses fishing line. Respectfully, no support is provided in the Office Action or in the references for a conclusion that wire used for a stent or fishing line constitutes a tether. Similarly, nothing in either reference suggests use in orthopedic treatment, and nothing in either reference suggests that their respective stent wire or fishing line can secure to adjacent bone portions. In fact, the Office Action specifically acknowledges that these references “fail to teach” use of their stent wire and fishing line “to attach bone portions.” See Office Action, page 8, lines 11-12.

Further, the Office Action has not shown that any part of Avellanet or Butters considered a “cord” has a tensile strength sufficient to maintain a desired distance or orientation of two bone portions. As discussed above, the Butters fishing line is not designed with such strength. The Avellanet reference does not have any disclosure to particular tensile strengths, and in fact notes that while tensile strength is one characteristic of interest in wire-drawing processes, the feature of interest in the Avellanet reference is flexibility. See column 2, lines 24-46, especially lines 40-43. The Avellanet stent wire is designed with a diameter of 85 ten-thousandths of an inch.

Such a thin wire cannot have the tensile strength recited in claim 1. Still further, there is no indication in either Avellanet or Butters of a “sheath,” much less one comprising fibers. Avellanet compresses individual wires, not fibers, into its stent wire, and Butters discloses an extruded melted layer of plastic in its fishing line. Compressed wire and plastic layers are not necessarily sheaths, and neither include fibers. A tether having the above characteristics simply is not found in Avellanet or Butters, or any legitimate combination of them.

Claims 2-35 are dependent from claim 1, and are thus allowable on that basis and, in many cases, on their own merit. For example, considering claims 2 and 3, what the Office Action erroneously considers a “sheath” in Avellanet and Butters, respectively the nickel-titanium outer layer of the stent wire and the plastic outer layer of the fishing line, are permanently fixed to their inner layers. Those inner layers are not slidable or free to move with respect to their outer layers. Considering claims 5 and 6, contrary to the Office Action’s assertion Avellanet does not disclose single or multiple fibers for its inner layers. Rather, Avellanet specifically notes the necessity of using noble metals as the central wire in its stent wire. Further, in relation to claims 7 and 8, the central layer of Avellanet is not braided, contrary to the Office Action’s analysis. As to claim 9, Avellanet does not show fibers for its outer wire layer, but specifically requires nickel-titanium wires. As to claims 12 and 14, the Office Action states that Avellanet’s central wire is its radiopaque element. See Office Action, page 5, lines 8-9. Since the central wire is not woven into or wound around itself, the only logical conclusion is that the Office Action effectively acknowledges that Avellanet does not show the entire subject matter of claims 12 and 14.

As to claim 18, Holzhauer cannot be combined with Avellanet and Butters, as discussed above, and further they do not show a second sheath. Its water-ski rope appears to show an outer braid or weave 12 around an inner braid or weave 11. Item 11 can be either a cord or a sheath, but not both, and therefore not all elements of claim 18 are present in the cited references.

As to claim 19, Burke cannot be combined with Avellanet and Butters, as discussed above, and further they do not show a tether, or a tether attached to a plurality of bone portions. Rather, Burke discloses wires wrapped around a femur to hold a plate to the bone.

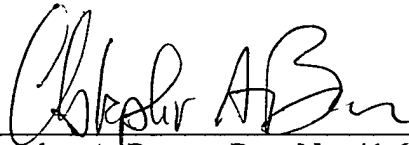
As to claim 30, Johnson cannot be combined with Avellanet and Butters, as discussed above, and further they do not show first and second bone fasteners that secure the cord to the first and second bone portions. Johnson shows tacks having a seat in which a wire can fit. Using the Johnson tack with the Avellanet stent wire or the Butters fishing line, the Johnson tack contacts the outer layer of the stent wire or fishing line. There is nothing in the Johnson reference that suggests that the tack secures the internal layer of the stent wire or fishing line, especially insofar as neither Avellanet nor Butters disclose exposing the internal layers, nor providing an internal layer that can move with respect to an outer layer of the stent wire or fishing line. With respect to claims 31 and 32, similarly, the Johnson tack can only be secured to the outer layer of the stent wire or fishing line, and thus the combination of Johnson with Avellanet and Butters cannot show a first or second sheath not secured to the two bone portions, as in claims 31 and 32.

Claims 36 and 37 include features discussed above that are not shown in the combination of cited references made in the Office Action. Accordingly, they are also allowable on their own merit.

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken by the examiner that are not specifically addressed herein.

To summarize, the six references cited against the pending claims are non-analogous to them and to each other, there is no motivation outside of the present application to combine them and their disparate disclosures, there has been no presentation of any desirability of such combinations, and the combinations do not show all elements of the claims. For at least these reasons, the pending claims are allowable over the references relied on in the Office Action. A Notice of Allowance in this case is respectfully solicited.

Respectfully submitted,



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